



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/821,624

04/09/2004

Michael John Dunkley

53315-US-CNT

8935

1095

7590

03/04/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

03/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/821,624
Filing Date: April 09, 2004
Appellant(s): DUNKLEY ET AL.

Guy V. Tucker
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/14/2008 appealing from the Office action mailed 10/16/2007.

Art Unit: 3771

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,069,819	VALENTINI et al.	1-1978
2003/0000523	CITTERIO	1-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 20, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Valentini et al. (US 4,069,819).

As to claim 20, Valentini discloses an aerosolization apparatus (fig.2) comprising a housing defining a chamber (B) having one or more air inlets (H), the chamber being sized to receive a capsule (C) which contains an aerosolizable pharmaceutical formulation (col.1 line 49); a puncturing mechanism (fig.3, E) within the housing, the puncturing mechanism comprising an alignment guide (L) and a puncture member (D), wherein the alignment guide comprises a surface (see labeled fig.3 attached below) adapted to contact the capsule while the puncture member is advanced into the capsule to create an opening in the capsule (col.2 lines 65-68, col.3 lines 1-10), and wherein the surface comprises one or more protrusions (see labeled fig.3, attachment below) for contacting the capsule, and an end (A) section associated with the housing, the end section sized and shaped to be received in a user's mouth or nose so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation that has exited the capsule through the opening created in the capsule (col.3 lines 10-16).

As to claim 27, Valentini discloses wherein surface comprises a passageway and wherein the puncture member slides within the passage (col.1 lines 46-49, col.2 lines 46-54).

As to claim 28, Valentini discloses wherein the inlet is shaped to create a swirling airflow within the chamber (col.3 lines 11-16).

Claim Rejections - 35 USC § 103

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. (US 4,069,819) in view of Citterio (US 2003/0000523 A1).

As Valentini discloses an aerosolization apparatus (see fig.2) comprising: a housing defining a chamber (B) having one or more air inlets (H), the chamber being sized to receive a capsule (C) which contains an aerosolizable pharmaceutical formulation (col.1 line 49); a puncturing mechanism (fig.3, M-T) within the housing, the puncturing mechanism comprising an alignment guide (L) and a puncture member (D), wherein the alignment guide comprises a surface (see labeled fig.3, attachment below) adapted to contact the capsule while the puncture member is advanced into the capsule to create an opening (col.2 lines 65-68, col.3 lines 1-10) in the capsule, and wherein at least a portion of the surface is sloped at an angle which is less than 55 degrees relative to the longitudinal axis of the capsule (see labeled fig.3); and an end section (A) sized and shaped to be received in a user's mouth or nose so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation that has exited the capsule through the opening created in the capsule (col.3 lines 10-16). Valentini however lacks the end section is removably connected to the housing and wherein the end section maybe removed from the housing to provide access to the chamber. However, Citterio (in figures 1-6) teaches an end section (3) of an aerosolization apparatus that is removably connected (by disengaging 5 and 8 from 2, see paragraphs 17-20) to a housing (2); Citterio further teaches the end section maybe removed from the housing to provide access to the chamber (see fig.1 and paragraph 26).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention

Art Unit: 3771

was made to modify Valentini in order to provide an end section that is removably connected to the housing because it is known in the art as taught by Citterio.

Additionally, Valentini lacks a detailed description of the claimed steps. However, Valentini discloses the structural limitations required to perform the method steps (see above paragraph). Valentini however lacks inserting the capsule in a chamber defined by a body and a removable end portion. However, Citterio teaches removable end portion. Thus, the instant method steps would have been an obvious result of using the apparatus of Valentini as modified by Citterio.

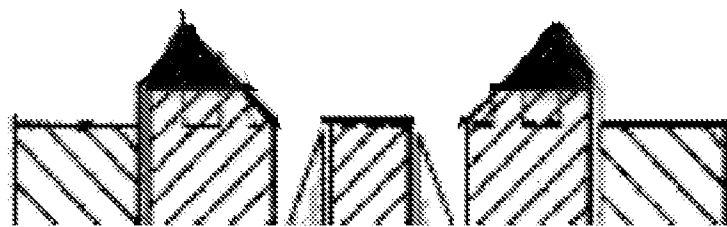
(10) Response to Argument

Applicant presents a single argument relating to the properness of the above rejections: that the Valentini reference does not disclose an alignment guide having a contact surface comprising one or more protrusions for contacting a capsule because there are no protrusions extending “from” the angled surfaced on which the capsule rests in Valentini. Examiner does not find this persuasive because there is no definition in the claims that makes it clear that the protrusion has to be a separate piece from the surface. For example, according to claim 20 and 31, the surface “comprises one or more protrusions,” which implies that the protrusions are part of the surface (as in Valentini).

The limitation of the protrusions extending somehow separately (or being completely surrounded) from the surface is not commensurate with the scope of the claims, thus within the broadest reasonable interpretation of the claims, one can make an arbitrary guide for setting where the surface and protrusion begin and end. For example, see the below figure taken from Figure 5 of Valentini, clearly identifying the protrusion as the solid black area. Either the

Art Unit: 3771

arbitrary horizontal surface underneath the protrusion or the remaining part of the angled surface indicated below the protrusion can be considered the “surface adapted to contact the capsule” comprising one or more protrusions (solid black area) because both lie in the location in which the capsule rests when being punctured. Examiner also notes that depending on the size of the capsule, it may or may not contact both the claimed surface and protrusion in the same way as the reference.



Detail from Fig. 5 of Valentini

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Kristen C. Matter/

Examiner, Art Unit 3771

Conferees:

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

Application/Control Number: 10/821,624

Page 8

Art Unit: 3771

/Janet C. Baxter/

TC 3700 TQAS